

MEDWATCH  
FDA eSubmitter Generated Form 3500A

For use by user-facilities,  
importers, distributors and manufacturers  
for MANDATORY reporting

Mfr Report #:
UF/Importer Report #: 1234567890-2023-00001
Form Code:
Exemption Number:

A. PATIENT INFORMATION						
1. Patient Identifier (In confidence)		2. Age at Time of Event, Date of Birth		3a. Sex	3b. Gender	4. Weight
5. Ethnicity ( ) Hispanic/Latino ( ) Not Hispanic/Latino						
6. Race [ ] Asian [ ] White [ ] American Indian or Alaskan Native [ ] Native Hawaiian or Other Pacific Islander [ ] Black or African American						
B. ADVERSE EVENT OR PRODUCT PROBLEM						
1. [ ] Adverse Event and/or [ ] Product Problem (e.g., defects/malfunctions)						
2. Outcomes Attributed to Adverse Event (Checked all that apply) [ ] Death [ ] Disability or Permanent Damage [ ] Life-threatening [ ] Congenital Anomaly/Birth Defect [ ] Hospitalization (initial or prolonged) [ ] Other Serious or Important Medical Events [ ] Required Intervention to Prevent Permanent Impairment/Damage						
3. Date of Event (dd-mmm-yyyy)				4. Date of this Report (dd-mmm-yyyy)		
5. Describe Event or Problem Additional event narrative.						
6. Relevant Tests/Laboratory Data, Including Dates						
7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)						
C. SUSPECT PRODUCT(S)						
D. SUSPECT MEDICAL DEVICE						
1. Brand Name			2. Common Device Name			
3. Manufacturer Name, City and State			4. Model #		Catalog #	
			Serial #		Lot #	
			Expiration Date (dd-mmm-yyyy)			
			Unique Identifier (UDI) #			
5. Operator of Device			6a. If Implanted, Give Date (dd-mmm-yyyy)		6b. If Explanted, Give Date (dd-mmm-yyyy)	
7a. Is this a Single-Use Device that was reprocessed and Reused on a Patient? ( ) Yes ( ) No			7b. If yes, Enter Name and Address of Reprocessor			
8. Was this device serviced by a third party? ( ) Yes ( ) No ( ) Unknown			9. Device Available for Evaluation? (Do not send to FDA) ( ) Yes ( ) No [ ] Returned to Manufacturer			
10. ConComitant Medical Products and Therapy Dates (Excludes treatment of event)						
E. INITIAL REPORTER						
1. Name and Address			2. Health Professional? ( ) Yes ( ) No			
			3. Occupation			

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	<b>4. Initial Reporter Also Sent Report to FDA?</b> ( ) Yes ( ) No ( ) Unk

**F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)**

<b>1. User Facility or Importer</b> ( ) User Facility (•) Importer	<b>2. User Facility/Importer Report Number</b> 1234567890-2023-00001	
<b>3, 4, and 5. User Facility or Importer Name/Address, Contact Person, and Phone Number</b>	<b>6. Date UF/Importer Became Aware of Event</b> (dd-mmm-yyyy)	
	<b>7. Type of Report</b> ( ) Initial (•) Follow-up #: 1	
	<b>8. Date of This Report</b> (dd-mmm-yyyy)	<b>9. Approximate Age of Device</b>
<b>10. Adverse Event Problem</b> (Refer to coding manual) Health Effect - Clinical Code: Health Effect - Impact Code: Medical Device Problem Code: Component Code:	<b>14. Manufacturer Name/Address</b>	
<b>11. Report Sent to FDA?</b> ( ) Yes ( ) No		
<b>12. Location Where Event Occurred</b>		
<b>13. Report Sent to Manufacturer?</b> ( ) Yes ( ) No		

**G. ALL MANUFACTURERS**

<b>1. Contact Office (and Manufacturing Site for Devices) or Compounding Outsourcing Facility</b>	<b>1. Contact Office - Manufacturing Site</b>	
<b>2. Report Source</b> (Check all that apply) [ ] Foreign [ ] Health Professional [ ] Study [ ] User Facility [ ] Literature [ ] Company Representative [ ] Consumer [ ] Distributor/Importer [ ] Other	<b>3. Date Received by Manufacturer</b> (dd-mmm-yyyy)	
	<b>4. Premarket Identification</b> PMA/510(k): [ ] Combination Product Device BLA:	
	<b>5. If IND/PreANDA, Give Protocol #</b>	
<b>6. Type of Report</b> [ ] 5-day [ ] Periodic [ ] 7-day [ ] Initial [ ] 15-day [ ] Follow-up [ ] 30-day	<b>7. Adverse Event Term(s)</b>	<b>8. Manufacturer Report Number</b>

**H. DEVICE MANUFACTURERS ONLY**

<b>1. Type of Reportable Event</b> ( ) Death ( ) Serious Injury ( ) Malfunction [ ] Summary Report No. of Events Summarized:	<b>2. If Follow-up, What Type?</b> [ ] Correction [ ] Additional Information [ ] Response to FDA Request [ ] Device Evaluation	<b>3. Device Evaluated by Manufacturer?</b> ( ) Yes ( ) No
<b>4. Device Manufacture Date</b> (dd-mmm-yyyy)	<b>6. Adverse Event Problem</b> (Refer to coding manual) Health Effect - Clinical Code: Health Effect - Impact Code: Medical Device Problem Code: Component Code: Type of Investigation: Investigation Findings:	
<b>5. Labeled for Single Use?</b> ( ) Yes ( ) No		

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		Investigation Conclusions:	
<b>7. If Remedial Action initiated, Check Type</b> <div><div><input type="checkbox"/> Recall</div><div><input type="checkbox"/> Repair</div><div><input type="checkbox"/> Replace</div><div><input type="checkbox"/> Relabeling</div><div><input type="checkbox"/> Other</div></div> <div><div><input type="checkbox"/> Notification</div><div><input type="checkbox"/> Inspection</div><div><input type="checkbox"/> Patient Monitoring</div><div><input type="checkbox"/> Modification/Adjustment</div></div>			